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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766

27367 7590 05/18/2005

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EXAMINER	
HON, SOW FUN	

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/475,721	REIMINK ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03/11/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-20,31 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-20,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/18/05 has been entered.

Withdrawn Rejections

2. The 35 U.S.C. 102(b) and 103(a) rejections have been withdrawn due to Applicant's amendment dated 01/18/05.

New Rejections

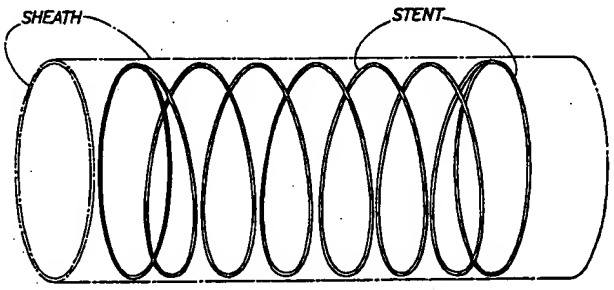
Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-2, 6-7, 10, 13-14, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (US 5,383,928).

Regarding claims 1-2, 10 Scott has a medical device (sleeve polymer-stent device) comprising a composite having an inorganic substrate (stainless steel stent) combined with a polymer sleeve (column 9, lines 55-60) which covers all of the

substrate, the polymer forming a sheath structure substantially different from the structure of the stent substrate, and providing the form of the device. See Fig. 3 of Scott below. The flexible composite component can be bent through a cross section of the flexible component composite.



Regarding claims 6-7, 13-14, Scott teaches that the polymer has an average thickness of 100 to 10000 microns (0.1 – 10 mm) which meets the claimed limitation of at least about 10 microns (claim 6), of from about 100 microns to about 2000 microns (claim 7), of from about 10 microns to about 500 microns (claim 13) and of from about 50 microns to about 300 microns (claim 14).

Regarding claims 16-19, although Scott fails to disclose that the flexible composite component can be bent about 180 degrees without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure; or that the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure, the stainless steel spring substrate (stent) of Scott (column 9, lines 55-

60) , as shown in the figure above, has the physical properties necessary to meet the limitations set forth above, as evidenced by Applicant's specification (page 14, lines 15-30), which teaches the same metal, stainless steel.

Claim Rejections - 35 USC § 103

5. Claims 3, 8, 9, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott as applied to claims 1-2, 6-7, 10, 13-14, 16-19 above, and further in view of Reimink et al. (US 5,910,170).

Regarding claim 3, Scott has been discussed above and teaches that the inorganic substrate (stent) comprises a metal. Scott fails to teach that the inorganic substrate (stent) comprises a ceramic.

Reimink teaches that ceramics are equivalent to metals as being suitable for use as a stent material (column 4, lines 5-15). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used a ceramic in lieu of metal as the inorganic substrate of Scott, in order to take advantage of the properties of the ceramic material for the desired end-use.

Regarding claims 8-9, 15, Scott fails to teach that the medical device comprises a heart valve prosthesis comprising a component that comprises the composite having the inorganic substrate and the polymer material (sleeve polymer-stent), that the polymer material has structure forming a hole, or that the composite component comprises leaflets.

Reimink teaches a heart valve prosthesis comprising a stent (column 1, lines 60-65) for carrying leaflets, wherein the stent includes openings and retaining holes used to couple material to the stent (column 2, lines 33-43).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used the component of Scott that comprises the composite having the inorganic substrate and the polymer material (sleeve polymer-stent) in a heart valve prosthesis, and hence to have provided holes as demonstrated by Reimink, in order to carry the leaflets for the heart valve prosthesis.

6. Claims 5, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott as applied to claims 1-2, 6-7, 10, 13-14, 16-19 above, and further in view of Gaterud et al. (US 5,522,882).

Scott has been discussed above and teaches that the medical device comprises a polymer forming a structure substantially different from the structure of the substrate, providing the form of the device (sheath). In addition, Scott teaches that other polymers can be used to form the polymer sleeve (column 10, lines 4-10). Scott fails to teach that the polymer is polycarbonate or that the polymer is rigid.

Gaterud teaches that polycarbonate is a suitable polymer for the sheath (column 6, lines 55-57) of a stent (column 6, lines 45-50). Polycarbonate is rigid. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have used polycarbonate as the rigid polymer in the composite of Scott, as taught by Gaterud, in order to take advantage of the properties of polycarbonate for the desired end-use.

7. Claims 5, 12, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott as applied to claims 1-2, 6-7, 10, 13-14, 16-19 above, and further in view of Ashiya et al. (US 5,947,925).

Scott has been discussed above and teaches that the medical device comprises a polymer forming a structure substantially different from the structure of the substrate, providing the form of the device (sheath). In addition, Scott teaches that ethylene vinyl acetate and other polymers can be used to form the polymer sleeve (column 10, lines 4-10). Scott fails to teach that the ethylene vinyl acetate polymer is rigid, crosslinked or that the polymer can also be polyethersulfone, polysulfone, polyurethane or polytetrafluoroethylene.

Ashiya teaches that the sheath may comprise a polymer such as ethylene vinyl acetate, polyacetal, polyethersulfone, polycarbonate, polysulfone (claim 5), crosslinked ethylene vinyl acetate (claim 31), polyurethane, polytetrafluoroethylene (claim 12) (column 6, lines 45-55) to provide the requisite flexural rigidity (claim 32), torsional rigidity and breaking strength, demonstrating that these polymers are all suitable for the polymer sheath.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have made the polymer sheath of Scott from crosslinked ethylene vinyl acetate, polyacetal, polyethersulfone, polycarbonate, polysulfone, polyurethane, polytetrafluoroethylene, rigid polymer, in order to obtain the desired flexural rigidity, torsional rigidity and breaking strength, as taught by Ashiya.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scott in view of Reimink as applied to claims 3, 8, 9, 15 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Scott in view of Reimink has been discussed above, and fails to teach that the composite further comprises a diamond-like carbon coating over at least a portion of the polymer.

Sumimoto teaches that a diamond-like carbon coating over the polymer provides good antithrombosis and durability properties (abstract).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a diamond-like carbon coating over at least a portion of the polymer of Scott in view of Reimink, in order to obtain good antithrombosis and durability properties, as taught by Sumimoto.

8. Claims 10-11, 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lenkei (US 4,597,767) in view of Reul et al. (US 4,263,680).

Regarding claims 10, 15, Lenkei teaches a medical device which comprises a heart valve prosthesis (column 4, lines 39-45) comprising a flexible composite component comprising leaflets, wherein each leaflet comprises an inorganic substrate which comprises a metal (stainless steel) foil (column 4, lines 19-25). The flexible component (stainless steel foil) can be bent through a cross section of the flexible component (stainless steel foil). Lenkei fails to teach that at least a portion of the inorganic substrate is covered by a polymer member.

Reul teaches that heart valve members advantageously comprise metal coated on both sides with blood-compatible synthetic material such as a polymer (epoxy compound) (column 4, lines 18-29).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have covered the stainless steel foil of Lenkei with a blood-compatible polymer member, in order to obtain a heart valve member with blood compatibility, as taught by Reul.

Regarding claim 11, Lenkei fails to teach the thickness of the metal foil.

Reul teaches that the heart valve member is preferably less than 300 microns (0.3 mm), which is within the claimed thickness range of less than about 500 microns, so that the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber (column 3, lines 40-50).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided the metal foil of Lenkei with a thickness of less than 500 microns, in order to obtain a heart valve member that can react almost instantaneously to the quickly changing heart chamber environment.

Regarding claims 16-19, although Lenkei fails to disclose that the flexible composite component can be bent about 180 degrees without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the flexible composite component beyond its elastic limit; that the flexible composite component can be bent about 60 degrees for about 40

million cycles without significant structural failure; or that the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure, the stainless steel foil of Lenkei (column 4, lines 19-25) has the physical properties necessary to meet the limitations set forth above, as evidenced by Applicant's specification (page 14, lines 15-30), which teaches the same metal, stainless steel.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lenkei in view of Reul as applied to claims 10-11, 15-19 above, and further in view of Sumitomo Electric Co. (Abstract, JP 59192366).

Lenkei in view of Reul has been discussed above and fails to teach that the composite further comprises a diamond-like carbon coating over at least a portion of the polymer.

Sumimoto teaches that a diamond-like carbon coating over the polymer provides good antithrombosis and durability properties (abstract).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided a diamond-like carbon coating over at least a portion of the polymer of Lenkei in view of Reul, in order to obtain good antithrombosis and durability properties, as taught by Sumimoto.

Response to Arguments

10. Applicant's arguments with respect to claims 1-3, 5-20, 31-32 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon
Sow-Fun Hon
05/02/05

HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772
5/13/05